Appendix A – K110344 Section 5; Summary Additional Information Response.

**510(k) Summary**

JUN 2 4 2011

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: December 16, 2010

Submitter: INO Therapeutics/Ikaria
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Madison, Wisconsin 53718

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Device: Trade Name: INOmax DS (Delivery System)

Common/Usual Name: Nitric Oxide Administration Apparatus (primary)
Nitric Oxide Administration Apparatus, Back-up System
Nitric Oxide Analyzer
Nitrogen Dioxide Analyzer

Classification Names: Apparatus, Nitric Oxide Delivery, or Apparatus, Nitric Oxide Backup Delivery, Class II – 21 CFR 868.5165

Product Code: MRN (Primary), MRQ, MRP

Predicate Device(s): **INOmax DS**$_{IR}$ K061901, K070867, K071516, K080484, K081691, K090958, K092545, K093922

Device Description: The INOmax DS$_{IR}$ uses a "dual-channel" design to ensure the safe delivery of INOmax. The first channel has the delivery CPU, the flow controller and the injector module to ensure the accurate delivery of NO. The second channel is the monitoring system, which includes a separate monitor CPU, the gas cells (NO, $NO_2$, and $O_2$ cells) and the user interface including the display and alarms. The dual-channel approach to delivery and monitoring permits INOmax delivery independent of monitoring but also allows the monitoring system to shutdown INOmax delivery if it detects a fault in the delivery system such that the NO concentration could become greater than 100 ppm.

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Intended Use:

The INOmax DS delivery system delivers INOmax® (nitric oxide of inhalation) therapy gas into the inspiratory limb of the patient breathing circuit in a way that provides a constant concentration of nitric oxide (NO), as set by the user, to the patient throughout the inspired breath. It uses a specially designed injector module, which enables tracking of the ventilator waveforms and the delivery of a synchronized and proportional dose of NO. It may be used with most ventilators.
The INOmax DS provides continuous integrated monitoring of inspired $O_2$, $NO_2$, and NO, and a comprehensive alarm system.
The INOmax DS incorporates a battery that provides up to 6 hours of uninterrupted NO delivery in the absence of an external power source.
The INOmax DS includes a backup NO delivery capability that provides a fixed flow of 250 mL/min of NO which along with user supplied 10 L/min of oxygen provides 20 ppm in the gas flow to a patients breathing circuit. It may also use the INOblender for backup.
The target patient population is controlled by the drug labeling for INOmax and is currently neonates. The primary targeted clinical setting is the Neonatal Intensive Care Unit (NICU) and secondary targeted clinical setting is the transport of neonates.

Technology:

All revisions of INOmax $DS_{IR}$ utilize component technology to deliver Nitric Oxide gas to the patient. The components consist of the Delivery System unit, the blender, a stand/cart and the NO gas tanks.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The testing concluded four requirements necessary for the operation of the INOmax $DS_{IR}$ and Vapotherm Precision Flow system to be compatible:

$O_2$ dilution

The measured $O_2$ was within $\pm$ 4% v/v of the expected value (see Pass/Fail Table on page 8; does not include tolerance of the Precision Flow).

INOmax $DS_{IR}$ delivery accuracy

The measured values were $\pm$ 15% of setting or 1.3 ppm whichever is greater which is within specification of the INOmax $DS_{IR}$ (see Pass/Fail Table on page 8).

$NO_2$ generation

The maximum generated $NO_2$ was at 80 ppm and 100% oxygen, as would be expected. $NO_2$ levels did not exceed 1.3 ppm on any of the flow settings (per INOmax label < 3 ppm on 100% $FiO_2$ and any dose setting). The maximum generated $NO_2$ at 40 ppm

and 60% oxygen was 0.4 ppm (worse case per FDA guideline of < 1 ppm on 60% $FiO_2$ at 40 ppm dose setting).

Backup Delivery

The delivered NO during backup delivery was within 5% (see Pass/Fail table, NO Measured section) of the INOmax DSIR specification at flow rates above 5 L/min. Measured $NO_2$ levels did not exceed 0.2 ppm on any settings tested and 100% oxygen (per INOmax label < 3 ppm on 100% $FiO_2$ and any dose setting). The measured $O_2$ was within $\pm$ 3% v/v of the expected value (see Pass/Fail table 100% Oxygen section of test report).

The INOmax DS revision complies to "Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer" (January 24, 2000) FDA-1157

The results of testing validated that the additional interface to the Vapotherm Precision Flow system did not alter the safety or effectiveness of the INOmax DS operation.

Summary of Clinical Tests:

The subject of this premarket submission, INOmax $DS_{IR}$ interfaced to Vapotherm Precision Flow did not require clinical studies to support substantial equivalence.

Comparison of the Similarities and Differences with the Predicate Device.

Other than the item listed below, all functional/technological characteristics remain the same between the reviewed INOmax $DS_{IR}$ and the predicate INOmax $DS_{IR}$.

Similarities:

No functional or technological change was made to INOmax $DS_{IR}$ for this 510(k) submission. The INOmax $DS_{IR}$ submitted for this review retains the same as the predicate device(s).

Differences:

Labeling change; listing and connection criteria for Vapotherm Precision Flow as an accepted interface for INOmax DSIR to be added in the INOmax $DS_{IR}$ Instructions for Use (IFU).

Conclusion: INO Therapeutics/Ikaria considers the INOmax $DS_{IR}$ to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Larry Lepley
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INO Therapeutics
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Madison, Wisconsin 53718

JUN 24 2011

Re: K110344
Trade/Device Name: INOmax DS
Regulation Number: 21 CFR 868.5165
Regulation Name: Nitric Oxide Administration Apparatus
Regulatory Class: II
Product Code: MRN
Dated: June 2, 2011
Received: June 3, 2011

Dear Mr. Lepley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: INOmax DS

Indications for Use:

The INOmax DS delivery system delivers INOmax® (nitric oxide for inhalation) therapy gas into the inspiratory limb of the patient breathing circuit in a way that provides a constant concentration of nitric oxide (NO), as set by the user, to the patient throughout the inspired breath. It uses a specially designed injector module, which enables tracking of the ventilator waveforms and the delivery of a synchronized and proportional dose of NO. It may be used with most ventilators.

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Prescription Use_X___ AND/OR Over-The-Counter Use_
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110344